SODIUM CHLORIDE- sodium chloride injection, solution
Spectra Medical Deviecs, LLC

Sodium Chloride Injection

0.9% Sodium Chloride

Injection, USP

Rx only

DESCRIPTION

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

0.9% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride and water for injection. Each mL contains sodium chloride 9 mg. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. 0.308 mOsmol/mL (calc.). 0.9% Sodium Chloride Injection, USP contains no preservatives. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. The pH range is 4.5 to 7.0. The glass ampules made up of Type I glass are used as a primary container for the drug product.
Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.

CLINICAL PHARMACOLOGY

Sodium chloride in water dissociates to provide sodium (Na+) and chloride (Cl-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na) and chloride (Cl) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by 0.9% Sodium Chloride Injection, USP when used only as an isotonic vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in neonates and very small infants.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and

sodium (Na+) plays a major role in maintaining physiologic equilibrium.

INDICATION AND USAGE

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

PRECAUTIONS

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy Category C

Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Injection, USP. It is also not known whether sodium chloride injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride injection containing additives should be given to a pregnant woman only if clearly needed.

Pediatric Use

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers, discard unused portion.

ADVERSE REACTIONS

Reactions which may occur because of this solution, added drugs or the technique of

reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of carbohydrate, sodium chloride or fluid overload except possibly in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures. See PRECAUTIONS and ADVERSE REACTIONS.

DOSAGE AND ADMINISTRATION

The volume of the preparation to be used for diluting or dissolving any drug for injection, is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.
This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

HOW SUPPLIED

0.9% Sodium Chloride Injection, USP is supplied in the following:

Size	Container	NDC
5 mL	Glass ampules packed in carton of 25 each	65282-1505-1
10 mL	Glass ampules packed in carton of 25 each	65282-1510-1

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufactured for:

Spectra Medical Devices, LLC
Wilmington, MA 01887

(978) 657-0889

By:

Huons Co., Ltd.

100 Bio valley-ro

Jecheon-si

Chungcheongbuk-do, 27159

Republic of Korea

XX#### Rev. #
MM/YY

Principal Display Panel - 5 mL Carton Label

Rx only

25 Single-dose ampules

Each single-dose ampule contains 5 mL NDC 65282-1505-1

0.9% Sodium Chloride Injection, USP

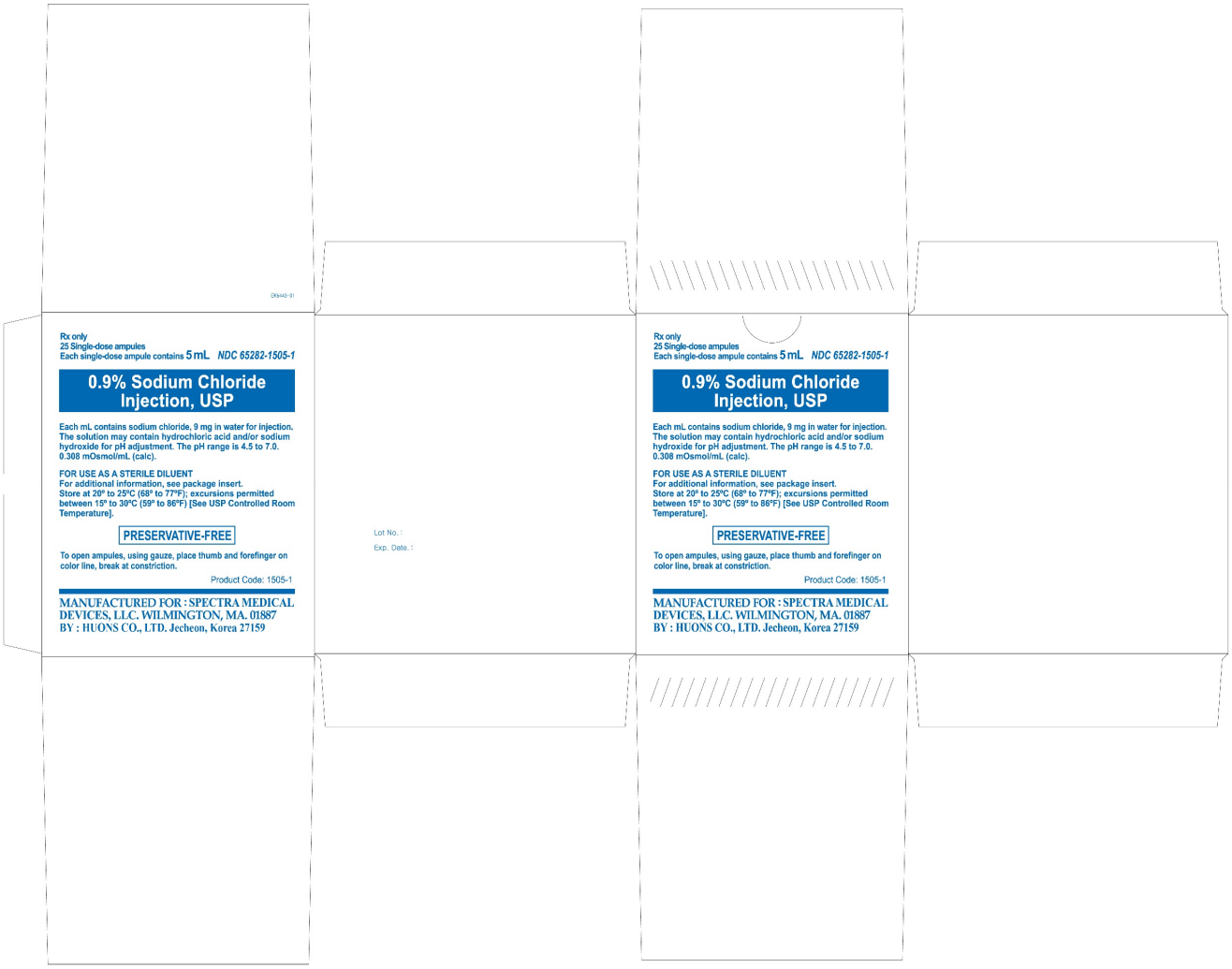
Each mL contains sodium chloride, 9 mg in water for injection. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. The pH range is 4.5 to 7.0. 0.308 mOsmol/mL.

FOR USE AS A STERILE DILUENT

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F)
[See USP Controlled Room Temperature],

PRESERVATIVE-FREE
To open ampules, using gauze, place thumb and forefinger on color line, break at constriction.
Product Code: XXXX-Y
MANUFACTURED FOR: SPECTRA MEDICAL DEVICES, LLC. WILMINGTON, MA. 01887

BY: HUONS. CO., LTD. Jecheon, Korea 27159



Principal Display Panel - 5 mL Ampule Label

NDC 65282-1505-1

5 mL Ampule

0.9% Sodium Chloride Injection, USP

0.308 mOsmol/mL (calc)

Rx only Single-dose

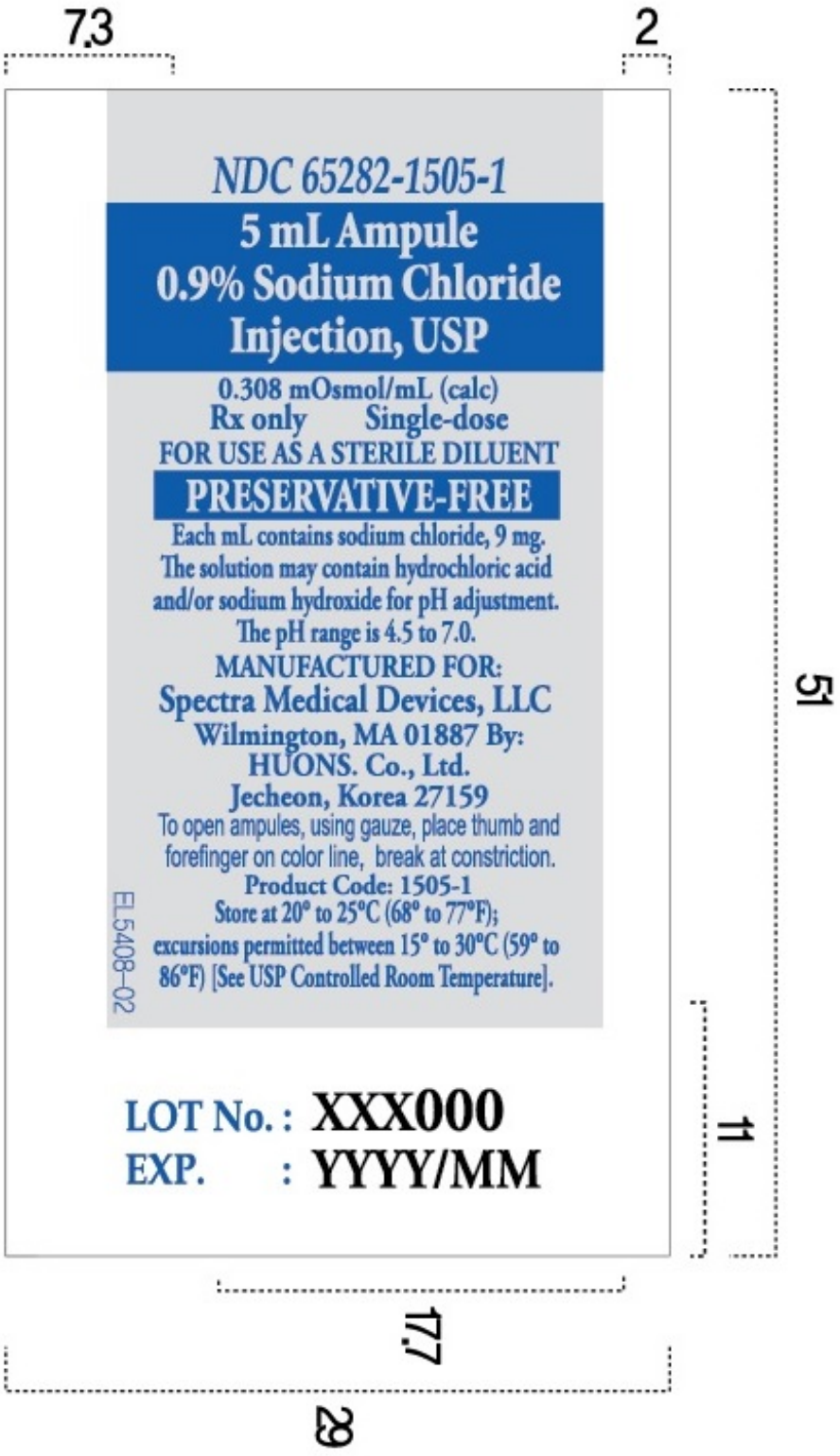
FOR USE AS A STERILE DILUENT

PRESERVATIVE-FREE

Each mL contains sodium chloride, 9 mg. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment.
The pH range is 4.5 to 7.0.
MANUFACTURED FOR:
Spectra Medical Devices, LLC.

Wilmington, MA 01887

By:
Huons. Co., Ltd.
Jecheon, Korea 27159
To open ampules, using gauze, place thumb and forefinger on color line, break at constriction.
Product Code: XXXX-Y
Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F)
[See USP Controlled Room Temperature].
LOT No.: XXX000
EXP.: YYYY/MM



Principal Display Panel - 10 mL Carton Label

Rx only
25 Single-dose ampules
Each single-dose ampule contains **10 mL NDC 65282-1510-1**
0.9% Sodium Chloride Injection, USP

Each mL contains sodium chloride, 9 mg in water for injection. The solution may contain

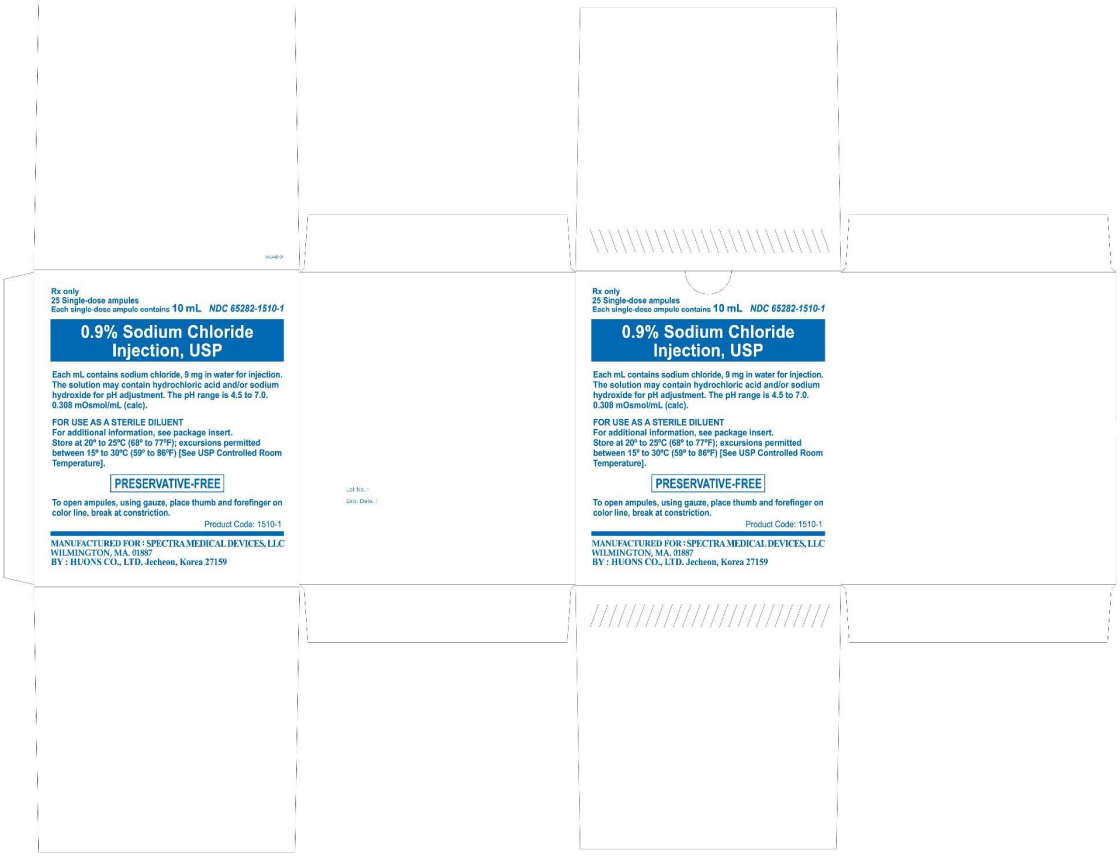
hydrochloric acid and/or sodium hydroxide for pH adjustment. The pH range is 4.5 to 7.0. 0.308 mOsmol/mL (calc).

FOR USE AS A STERILE DILUENT
For additional information, see package insert.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F)
[See USP Controlled Room Temperature].

PRESERVATIVE-FREE

To open ampules, using gauze, place thumb and forefinger on color line, break at constriction.
Product Code: XXXX-Y
MANUFACTURED FOR: SPECTRA MEDICAL DEVICES, LLC. WILMINGTON, MA.01887
BY : HUONS CO., LTD. Jecheon, Korea 27159



Principal Display Panel - 10 mL Ampule Label

NDC 62582-1510-1

10 mL Ampule

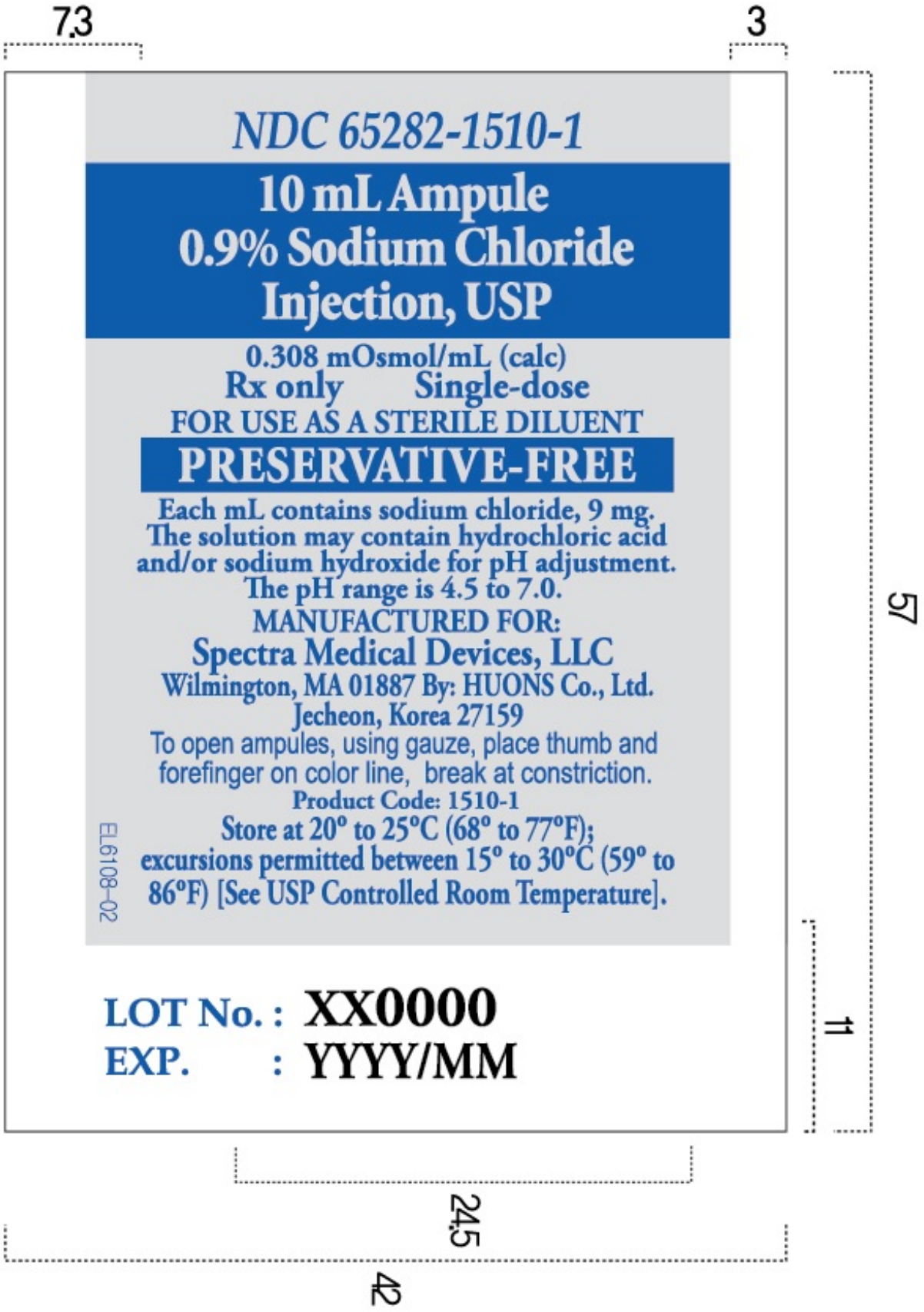
0.9 % Sodium Chloride Injection, USP

0.308 mOsmol/mL (calc)
Rx only Single-dose
FOR USE AS A STERILE DILUENT
PRESERVATIVE-FREE
Each mL contains sodium chloride, 9 mg.
The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment.
The pH range is 4.5 to 7.0.
MANUFACTURED FOR:
Spectra Medical Devices, LLC

Wilmington, MA 01887

By:

Huons Co., Ltd.
Jecheon, Korea 27159
To open ampules, using gauze, place thumb and forefinger on color line, break at constriction.
Product Code: XXXX-Y
Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F)
[See USP Controlled Room Temperature].
LOT No.: XX0000
EXP.: YYYY/MM



SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65282-1510
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65282-1510-1	5 in 1 CARTON	07/21/2017	
1		5 in 1 TRAY		
1		10 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206171	07/21/2017	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65282-1505
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start**	**Marketing End**

#	Item Code	Package Description	Date	Date
1	NDC:65282-1505-1	5 in 1 CARTON	07/21/2017	
1		5 in 1 TRAY		
1		5 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206171	07/21/2017	

Labeler - Spectra Medical Deviecs, LLC (118301171)

Registrant - Spectra Medical Devices, LLC (118301171)

Establishment

Name	Address	ID/FEI	Business Operations
Huons Co., Ltd.		631099384	manufacture(65282-1505, 65282-1510)

Revised: 1/2024 Spectra Medical Deviecs, LLC